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Editorial

The European cystic fibrosis patient registry: The power of sharing data

This special supplement of the *Journal of Cystic Fibrosis* is the first of two supplements dedicated to the European Coordination Action for Research in Cystic Fibrosis (EuroCareCF) project. Funded by the Sixth Framework Programme of the European Commission, EuroCareCF provided individuals working to defeat the common, life-shortening genetic disease cystic fibrosis (CF) with opportunities to interact, exchange information and collaborate to achieve common goals. The major goals of the project were first, to improve the survival and quality of life of CF patients and second, to optimize clinical management and therapy development.

To achieve its goals, EuroCareCF was organized into a series of eight workpackages addressing different areas of CF research and patient care (Fig. 1). These areas ranged from basic research and therapy development to clinical research, patient care and the development of a European CF patient registry. Through a variety of activities, such as meetings, workshops and "hands-on" training courses, workpackages produced reports and consensus guidelines, built networks of CF professionals, provided expert training and distributed key resources to the CF community. Some reports and consensus guidelines have already been published (e.g. Refs. 1–6). Most will be published in the second EuroCareCF supplement for the *Journal of Cystic Fibrosis*. However, this supplement is devoted to the report of EuroCareCF workpackage 2 (European CF Patient Registry) on the demographics of CF in 35 European countries (7).

The aim of EuroCareCF workpackage 2 was to create a uniform and ethically compliant European registry of CF patients. At the outset of the EuroCareCF project, the scope of this Registry was limited to CF patients from 22 countries within the European Union. However, through collaboration with the European Cystic Fibrosis Society (ECFS), the scope of the Registry was enlarged substantially to include CF patients from other countries in Europe, member and non-member states of the European Union alike.

The scale of the task facing EuroCareCF workpackage 2 was enormous. First, it included framing templates and guidelines for obtaining patient consent in each country that satisfied the requirements of the European Data Protection Directive 95/46/EC, while remaining compliant with local laws and ethics (see the webpages of EuroCareCF workpackage 2; http://www.eurocarecf.eu/). These consent templates and procedures continue to be used by the ECFS in their management of the European CF Patient Registry after the end of the EuroCareCF project (http://www.ecfs.eu/ecfs_supported_initiatives/european_cf_registry/ethics_conf). Second, obtaining the approval of CF patients to collect anonymised data. Third, agreeing with both the CF Foundation (USA) and the ECFS common definitions for demographic variables to ensure that the collected data would be truly comparable, while at the same time making the data "future-proof" to facilitate international comparisons. Fourth, collecting and analysing demographic data for CF patients from 35 European countries. Finally, producing a report on the demographics of CF in Europe (7).

The enthusiasm to contribute to the European CF Patient Registry was tremendous. Prior to the start of EuroCareCF, with the exception of a few countries, most countries in Europe lacked formal CF patient registries. To facilitate the analysis and comparison of data from different European countries, EuroCareCF workpackage 2 focused on collecting demographic data (e.g. month and year of birth, age at diagnosis, gender and genotype). In total, forty one European countries (Armenia, Austria, Belarus, Belgium, Bosnia, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Latvia, Lithuania, Luxembourg, Macedonia, Malta, Moldova, Netherlands, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and United Kingdom) joined the European CF Patient Registry. Of these countries, all but six countries contributed data for the EuroCareCF report on the demographics of CF in Europe (7). A special feature of this report is that demographic data for individual countries are compared side-by-side with demographic data for all of Europe (i.e. 29,095 patients from 35 countries).

In his commentary (8), Nick Fahy (Head of the Health Information Unit, European Commission, Luxembourg) explains the significance of this report by EuroCareCF workpackage 2 as well as their analysis of the effects of European Union membership on the demographics of CF in Europe (9). My own view is that the European CF Patient Registry is of critical importance for the care of CF patients in Europe, providing vital information with which to assess the performance of healthcare systems in individual countries. Analysis of collected data permits the identification of CF centres that perform especially well with the result that best practice in patient care can be shared widely to the benefit of all CF patients. The Registry also has a crucial role to play in the identification of

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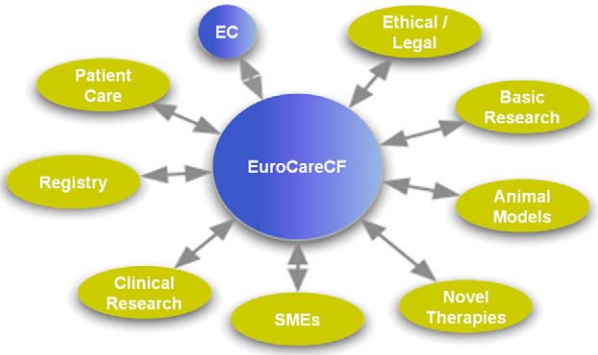

Fig. 1. The organization of the EuroCareCF project. EuroCareCF consisted of eight workpackages undertaking programmes of work to address specific aspects of patient care and therapy development and a coordinating workpackage that managed the project, promoted interactions between project participants and stakeholders and communicated with the European Commission (EC). The eight workpackages of EuroCareCF were Optimising Patient Care & CF Team Work; European Cystic Fibrosis Patient Registry; Coordination of Clinical Research; Small and Medium-Sized Enterprises (SMEs) Group; Novel Therapies; Animal Models; Integration of Fundamental Research and Ethical/Legal/Social Issues.

CF patients for mutation-specific clinical trials of new therapies for CF. The close cooperation that has developed between the European CF Patient Registry and the European Clinical Trial Network (10) is therefore very welcome. Given the importance of the European CF Patient Registry, I am especially delighted that the ECFS has agreed to fund and manage this Registry after the end of the EuroCareCF project.

During the course of the project, EuroCareCF workpackage 2 received requests from several countries outside of Europe to join the European CF Patient Registry. Because of the nature of the project and its funding from the European Commission, it was regrettably not possible for these countries to join the Registry. In the future, the CF community should strive towards a global CF Patient registry with common data definitions. The development of such a database would improve further patient care and therapy development. It would also provide another example of CF serving as a paradigm for other rare diseases.

I would like to take this opportunity to thank many wonderful colleagues for their wide-ranging contributions to the success of the European CF Patient Registry. Anil Mehta, Milan Macek and Gita Mehta, the leader, deputy leader and project manager, respectively, of EuroCareCF workpackage 2, who undertook all the work listed above, and much more besides, to establish the European CF Patient Registry. Marie Johannesson and Stuart Elborn, Presidents of the ECFS during the period of the EuroCareCF project, for their vision of a European CF Patient Registry and their commitment to supporting the Registry after the end of funding from the European Commission, respectively. The Registry Steering Committee, including Hanne Olesen, Eitan Kerem, Martin Stern and Laura Viviani as well as colleagues from the ECFS Registry Working Group for generously sharing data and developing data standards. Bob Beall, Preston Campbell, Bruce Marshall and colleagues from the US CF Foundation for generously sharing their registry software, PortCF and for providing invaluable help and advice about CF patient registries. Herman Nys and Kris Dierickx of EuroCareCF workpackage 8 (Ethical/Legal/Social Issues) for their advice about patient consent. Representatives of 41 European countries for generously agreeing to share CF patient data to build a truly European CF Patient Registry. EuroCareCF was supported by the European Union Sixth Framework Programme (contract no. LSHM-CT-2005-018932, EuroCareCF).

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